

REMARKS

Claims 1 and 5-40 were pending in the present application prior to entry of the present amendment. Claims 9, 12-13, 22-28, and 31-38 were previously withdrawn from consideration as drawn to a non-elected invention. The Examiner withdraws claims 39-40 alleging that election of claims by original presentation is the basis for the withdrawal. Applicant disagrees and believes that claims 39-40, added in Applicant's amendment mailed May 26, 2004, fall within the elected invention and should therefore be considered. Applicant has marked claims 39-40 as "withdrawn" in the listing of claims at page 7 (pursuant to the Examiner's withdrawal of them), but requests reconsideration of this withdrawal. By virtue of this response, claims 16-17 have been cancelled, without prejudice; claim 1 has been amended; and new claims 41-44 have been added. Applicant believes that new claims 41-44 fall within the elected invention. Support for new claim 41 can be found at least at paragraphs [0084]; support for new claim 42 can be found at least at paragraph [0065]; support for new claim 43 can be found at least at paragraph [0095] and [0120]; and support for new claim 44 can be found at least at paragraph [0123].

Accordingly, claims 1, 5-8, 10-11, 14-15, 18-21, 29-30, and 41-44 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicant requests rejoinder of methods claims that recite all the limitations of allowed composition claims. In re Ochiai.

Regarding Withdrawal of the Finality of the Office Action

The finality of the Office Action mailed April 28, 2005 was deemed withdrawn as indicated in an Examiner-Initiated Interview Summary signed by Examiner Housel and sent via facsimile to Applicant on August 19, 2005, *after* the three month date for response. Even though the withdrawal of the finality was necessitated by a USPTO error and was sent to Applicant *after* the three month date for response, the due date for response was not reset. It is noted for the record that Applicant's representative initiated telephone calls to Examiner Housel regarding this issue on

June 21, 2005; June 23, 2005; July 22, 2005; August 2, 2005; August 12, 2005; and August 18, 2005, and sent an e-mail communication to Examiner Housel on August 19, 2005. Examiner Housel initiated a telephone call to Applicant's representative on June 24, 2005 indicating that the finality would be withdrawn, and not indicating if the due date for response would be reset. The withdrawal of the finality was not initiated until August 19, 2005.

Based on the initial Statutory period as indicated in the Office Action mailed April 28, 2005, Applicant has submitted a Petition for Extension in time along with the appropriate fee. In view of the above, Applicant respectfully requests that the due date for response be reset to reflect the August 19, 2005 withdrawal of finality, thereby obviating the need for a Petition for Extension in time and fee.

Regarding Priority

Applicant acknowledges the acceptance of the claimed domestic priority under 35 U.S.C. 119(e).

Regarding Information Disclosure Statement

Applicant acknowledges the consideration of the Information Disclosure Statement filed on October 1, 2004 and thanks the Examiner for the returned initialed copy. Applicant respectfully requests consideration of the Information Disclosure Statement filed concurrently herewith and requests that the Examiner return the initialed copy.

Rejection of Claims Under 35 U.S.C. § 103(a)

Claims 1, 5-8, 10, 11, 14-21, 29 and 30 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lusky et al. (WO9961638) in view of Matthews et al. (Journal of General Virology (1999) 80, 345-353). Applicant points out that U.S. Patent No. 6,479,290 appears to be filed under Section 371 based on WO99/61638 and was previously cited by this Examiner.

Applicant traverses this rejection. Applicant does not agree or concede that a *prima facie* case of obviousness has been established and submits that the invention is non-obvious in view of the cited references. In order to establish a *prima facie* case of obviousness, there has to be, *inter alia*, some motivation or suggestion provided by the references, or in combination with the knowledge available to the skilled artisan, to modify the art cited or to combine reference teachings. Applicant submits that there is no motivation to combine references and, even if combined, the combination of references does not provide a reasonable expectation of successfully arriving at the claimed invention and does not teach or suggest the claimed invention.

Lusky et al. is cited by the Examiner as allegedly teaching bovine adenoviral expression vectors comprising a heterologous transgene. The Examiner states that Lusky et al. fail to teach the presence of an intron located 5' to the heterologous transgene to be expressed. Applicant submits that Lusky et al., which relate, in part, to encapsidation of adenovirus vectors, neither teach nor suggest the presently claimed invention. There is no disclosure or suggestion in Lusky et al. of a transgene that comprises a nucleic acid sequence susceptible to splicing events, or that comprises a splice junction sequence, much less of a replication-competent bovine adenovirus vector that comprises an intron 5' to such a transgene that is inserted into the E3 region of the vector. Applicant submits that there is no disclosure or suggestion in Lusky et al. of the presently claimed invention.

The Examiner alleges that Matthews et al. teach mammalian cell lines in which an adenovirus vector with a promoter-intron expression cassette expresses a rabies gene at much higher levels than vectors lacking the intron, and that vectors following intraperitoneal injection can induce a high level of rabies virus-neutralizing antibody. Applicant submits that there is no disclosure or suggestion in Matthews et al. of the claimed invention. There is no suggestion in Matthews et al. of any adenovirus vector comprising a transgene that comprises a nucleic acid sequence susceptible to splicing events, or that comprises a splice junction sequence. There is no suggestion in Matthews et al. of a replication-competent bovine adenovirus vector comprising such a transgene inserted in the E3 region.

Applicant invites the Examiner's attention to Matthews' Abstract at page 345 which states that the adenovirus vector used is replication-defective. Matthews et al. plasmid pMH5 (see Matthews et al. page 346) is referenced as being described in Addison et al. (1997, J. of Gen. Virology, vol. 78:1653-1661). Addison et al. describe plasmid pMH5 as containing human Ad5 nucleotide sequences (see Addison et al. page 1655). Thus, Matthews et al. disclose a replication-defective human adenovirus based vector. The presently claimed invention recites, in part, a replication-competent bovine adenovirus vector wherein a transgene is inserted into the E3 region of the vector.

Applicant submits that there would be no expectation of successfully arriving at the claimed invention, which recites in part, a replication-competent bovine adenovirus vector comprising an intron and a heterologous transgene, wherein said transgene comprises a nucleic acid sequence that is susceptible to splicing events and is inserted into the E3 region of said vector, based on the teachings of Matthews et al., which describes a replication-defective human adenovirus based vector. Regarding the bovine adenovirus E3 region, as is stated in Zakhartchouk, et al. (1998, Virology, vol. 250:220-229) at page 220, one of the distinctive features of bovine adenovirus E3 region is its small size. Zakhartchouk, et al. also note that analysis of the bovine E3 region suggests that the E3 region may code at least four proteins, one of which shows limited homology to human adenovirus 5 (HAV5). Given the reported features of bovine adenovirus E3 region, one of skill in the art would have no expectation of successfully arriving at the claimed invention based on the Matthews et al. disclosure of a replication-defective human adenovirus vector.

Further, Applicant invites the Examiner's attention to Matthews et al., page 347, the right column under Results section. This section refers to replication-defective human adenovirus vectors in which the expression of rabies virus glycoprotein (RG) was driven by the strong MCMV promoter in combination with an intron sequence. It is stated by Matthews et al. that numerous attempts to rescue the cassette into a virus failed. It is stated by Matthews et al. that the result suggested that the failure to rescue functional vectors was due to toxicity of the over-expressed RG.

Matthews et al. constructed a 293-based cell line which expressed a repressor protein and expression cassettes containing repressor-binding sequences, to reduce expression and toxicity of RG in transfected cells. Matthews et al. have no teachings or suggestions of the claimed invention, which recites in part, a replication-competent bovine adenovirus vector comprising an intron and a heterologous transgene, wherein said transgene comprises a nucleic acid sequence that is susceptible to splicing events and is inserted into the E3 region of said vector.

There are no teachings or suggestions in either of Lusky et al. or Matthews et al. of the claimed invention. There is no motivation provided in either of Lusky et al. or Matthews et al. to combine references and, even if combined, the combination of references does not provide a reasonable expectation of successfully arriving at the claimed invention.

In view of the above, Applicant respectfully requests withdrawal of this Section 103 rejection of claims.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 293102002900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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